K012934

SEP 2 8 2001

510(k) Summary

CELL-DYN 3200 System with Absolute and Percent Reticulocyte

Submitted by: Abbott Laboratories
5440 Patrick Henry Drive
Santa Clara, CA 95054

Contact Person: John Dean
Phone: (408) 567-3430
Fax: (408) 567-3523

Date Prepared: August 30, 2001

Proprietary Name CELL-DYN 3200 System with Absolute and Percent Reticulocyte

Common Name: Automated Hematology Analyzer

Classification Name: Automated Differential Cell Counter (21 CRF 864.5220)

Predicate Device: CELL-DYN 4000 System, K961439/S1

Intended Use:

The CELL-DYN 3200 System with Absolute and Percent Reticulocyte count is a multiparameter, automated hematology analyzer designed for in vitro diagnostic use in clinical laboratories and physician office laboratories.

Device Description:

The CELL-DYN 3200 System has three main modules: 1) the Analyzer, which aspirates, dilutes and analyzes each whole blood specimen; 2) the Data Module, which automatically analyzes, stores, and reports specimen results; 3) the Display Station, which consists of a color monitor and pressure-sensitive keypad for selecting the displayed commands that operate the system. The Analyzer and Data Module are housed in a single chassis. The Display Station is a stand-alone module.

The analyzer counts, sizes and classifies blood cells by Optical Laser Light Scatter. The CELL-DYN 3200 System uses a Helium-Neon laser as the optical light source. The Optical Bench detects light in the form of scatter from blood cell surfaces and internal structures.

For the reticulocyte parameters, an off-line dilution of blood and Reticulocyte Reagent is prepared and stained for 15 minutes. The dilution is aspirated and the reticulocytes are counted in the WOC channel. Data are collected for scatter (0, 10, and 90 degree) as each cell passes through the laser beam.

The CELL-DYN 3200 System is designed to analyze EDTA-anticoagulated whole blood specimens and report the additional Absolute and Percent Reticulocyte Parameters.

The CELL-DYN 3200 System is designed to classify the following formed elements of EDTA-anticoagulated blood:

White blood Cell Parameters:	Red Blood Cell Parameters:
WBC -- White Blood Cell or Leukocyte Count NEU -- Neutrophil Absolute Count %N -- Neutrophil Percent LYM -- Lymphocyte Absolute Count %L -- Lymphocyte Percent MONO -- Monocyte Absolute Count %M -- Monocyte Percent EOS -- Eosinophil Absolute Count %E -- Eosinophil Percent BASO -- Basophil Absolute Count %B -- Basophil Percent Platelet Parameters: PLT -- Platelet Count MPV -- Mean Platelet Volume *PDW -- Platelet Distribution Width *PCT -- Plateletcrit	RBC -- Red Blood Cell or Erythrocyte Count HCT -- Hematocrit MCV -- Mean Cell Volume RDW -- Red Cell Distribution Width Hemoglobin Parameters: HGB -- Hemoglobin Concentration MCH -- Mean Cell Hemoglobin MCHC -- Mean Cell Hemoglobin Concentration Reticulocyte Parameters: **RETIC ABS-- Reticulocyte Absolute** **RETIC% -- Reticulocyte Percent of RBC Count**

* Clinical significance has not been established for these parameters. Therefore, they are not reportable in the U.S.
**For Laboratory Use Only, therefore it is not reportable.

Similarities and Differences:

The CELL-DYN 3200 and the CELL-DYN 4000 System are similar in that both systems enumerate reticulocytes in EDTA-anticoagulated whole blood using New Methylene Blue N dye and optical laser scatter. The two Reticulocyte Reagents enable both the CELL-DYN 3200 and the CELL-DYN 4000 Systems to count and classify reticulocytes. Blood specimens for the CELL-DYN 3200 are externally stained in an off-line preparation step with New Methylene Blue N that requires incubation prior to measurement, while the CELL-DYN 4000 system automatically aliquots Reticulocyte Reagent containing the dye when CBC + RETC or CBC + RETC, Resistant RBC test is selected. They are different in that the Analyzer and Data Module of the CELL-DYN 3200 are housed in a single chassis while the CELL-DYN 4000 has a stand-alone data station consisting of a monitor, CPU and keyboard.

Equivalency Data:

The data compiled to support the claim that the CELL-DYN 3200 System with Reticulocyte Percent (RETIC %) and Reticulocyte Absolute (RETIC ABS) parameters is substantially equivalent to the CELL-DYN 4000 System includes: background, carryover, linearity, precision, and accuracy. The data supports the claim that the CELL-DYN 3200 System with RETIC % and RETIC ABS parameters is substantially equivalent to the CELL-DYN 4000 System.

The background, carryover, linearity, precision, and accuracy data shows performance to manufacturer's specifications. Data was collected at an internal Abbott Diagnostics Division site.

Conclusion:

The CELL-DYN 3200 System with RETIC % and RETIC ABS parameters demonstrates substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 8 2001

Mr. John Dean
Manager, Regulatory Affairs
Abbott Laboratories
5440 Patrick Henry Drive
Santa Clara, California 95054

Re: K012934
Trade/Device Name: CELL-DYN® 3200 System with Absolute and Percent Reticulocyte
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: II
Product Code: GKZ
Dated: August 30, 2001
Received: August 31, 2001

Dear Mr. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K012934

Device Name: CELL-DYN® 3200 System with Absolute and Percent Reticulocyte

Indications for Use:

The CELL-DYN 3200® System with Absolute and Percent Reticulocyte is an automated, multiparameter hematology analyzer designed to classify the following formed elements of EDTA-anticoagulated blood:

White blood Cell Parameters:	Red Blood Cell Parameters:
WBC – White Blood Cell or Leukocyte Count NEU -- Neutrophil Absolute Count %N -- Neutrophil Percent LYM -- Lymphocyte Absolute Count %L -- Lymphocyte Percent MONO – Monocyte Absolute Count %M -- Monocyte Percent EOS -- Eosinophil Absolute Count %E -- Eosinophil Percent BASO -- Basophil Absolute Count %B -- Basophil Percent	RBC -- Red Blood Cell or Erythrocyte Count HCT -- Hematocrit MCV -- Mean Cell Volume RDW -- Red Cell Distribution Width Hemoglobin Parameters: HGB – Hemoglobin Concentration MCH -- Mean Cell Hemoglobin MCHC – Mean Cell Hemoglobin Concentration
Platelet Parameters: PLT – Platelet Count MPV -- Mean Platelet Volume *PDW -- Platelet Distribution Width *PCT -- Plateletcrit	Reticulocyte Parameters: **RETIC ABS -- Reticulocyte Absolute** **RETIC% -- Reticulocyte Percent of RBC Count**

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter Use ____

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K 010934